**Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products**

# DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT (FAMILY) FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the applicant)

**Under simplified application procedure**

## HG tegen fruitvliegjes

Product type(s) 19

Vinegar as included in the Union list of approved active substances

Case Number in R4BP: [BC-NE064153-50]

Evaluating Competent Authority: Belgium

Date: [05/11/2021]

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# 1 CONCLUSION

HG tegen fruitvliegjes is an attractant liquid against *Drosophila melanogaster* (adults) for non-professionnals. The product is intended to be used in a trap (small bottle). The user has to pour 5mL of the product, up to the volume indication mark in the 'trap'. The trap must be placed in the room.

For the biocidal product HG tegen fruitvliegjes it has been established that sufficient data have been provided to verify the outcome and conclusions and that all conditions are met to permit authorization of the biocidal product in accordance with article 25 of Regulation (EU) No 528/2012:

(a) the active substance contained in the biocidal product appears in Annex I, and no restrictions apply to the substance;
(b) the biocidal product does not contain any substance of concern;
(c) the biocidal product does not contain any nanomaterials;
(d) the biocidal product is sufficiently effective; and
(e) the handling of the biocidal product and its intended use do not require personal protective equipment.

**Composition and classification**

Vinegar is listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin. The biocidal product HG tegen fruitvliegjes contains 99.645% Vinegar. The biocidal product is not classified according to Regulation (EU) No. 1272/2008, and contains no substances of concern. Its handling does not require any personal protective equipment.

**Physico-chemistry**

The biocidal product HG tegen fruitvliegjes is a clear orange liquid with acidic / vinegar odour. Its density is 1.1 g/mL at 20°C and 101.3 kPa . The pH of the neat product is determined at 2.4-3.4.
The estimated shelflife is 2 years shelflife based on results of accelerated storage stability test in commercial package.

In line with the criteria for simplified authorisation, according to Article 25 of the BPR, the biocidal product has no physical hazards.

**Efficacy**

eCA assessed that the product HG tegen fruitvliegjes, has shown a sufficient efficacy for the use claimed:

- Indoor use by non-professionals against *Drosophila melanogaster* (adults) at an application rate of 5 mL/trap with a residual efficacy of 2 weeks and a maximum area to be treated of 60 $m^3$ (24 $m^2$).

# 2 ASSESSMENT REPORT

## 2.1 Summary of the product assessment

### 2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

| **Identifier**[1] | **Country (if relevant)** |
|---|---|
| | Belgium |

2.1.1.2 Authorisation holder

| | | |
|---|---|---|
| **Name and address of the authorisation holder** | **Name** | HG International BV |
| | **Address** | PJ Oudweg 41<br>NL 1314CJ Almere |
| **Authorisation number** | EU-0026224-0000 | |
| **Date of the authorisation** | 5/11/2021 | |
| **Expiry date of the authorisation** | 5/11/2031 | |

2.1.1.3 Manufacturer(s) of the products of the family

| | |
|---|---|
| **Name of manufacturer** | HG International BV |
| **Address of manufacturer** | PJ Oudweg 41<br>1314CJ Almere<br>The Netherlands |
| **Location of manufacturing sites** | Damsluisweg 70<br>1332 EJ Almere<br>The Netherlands |

2.1.1.4 Manufacturer(s) of the active substance(s)

| | |
|---|---|
| **Active substance** | Vinegar |
| **Name of manufacturer** | [redacted] |
| **Address of manufacturer** | [redacted] |
| **Location of manufacturing sites** | [redacted] |

1 Please fill in here the identifying product name from R4BP.

## 2.1.2 Product (family) composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

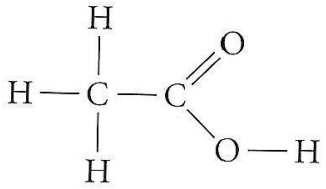
There is no product evaluated in connection with the approval of listing the active substance becasue the active substance Vinegar is included in Annex 1 of BPR for product type 19 benefiting from the food and feed derogation.
Biocidal products containing this type of active substances can apply under the simplified application (SA) procedure.

To apply for the SA procedure, the biocidal product (BP) must be eligible according to Article 25 of the Biocidal Products Regulation ((EU) No 528/2012 (BPR)):

- all the active substances contained in the BP appear in Annex I to the BPR and comply with the specified restrictions;
- the BP does not contain any substance of concern;
- the BP does not contain any nanomaterials;
- the BP is sufficiently effective;
- the handling of the BP and its intended use do not require personal protective equipment.

The active substance is Vinegar which is included on Annex I to the BPR (Regulation 2019/1819). The product "HG tegen fruitvliegjes" does not contain any substance of concern or nanomaterials (see Annex 3.6 for details). The efficacy is summarized in 2.2.5 and shows sufficient effectivity. The handling and intended use of HG tegen fruitvliegjes does not require personal protective equipment (see 2.1.3).

### 2.1.2.1 Identity of the active substance

| Main constituent(s) | |
|---|---|
| **ISO name** | Vinegar |
| **IUPAC or EC name** | Vinegar |
| **EC number** | - |
| **CAS number** | 8028-52-2 |
| **Index number in Annex VI of CLP** | Not applicable |
| **Minimum purity / content** | Excluding vinegar that is not food and excluding vinegar that contains more than 10 % acetic acid (whether or not it is food). |
| **Structural formula** | Natural substance vinegar<br>Maximum 10 % acetic acid in solution<br>  <br>Acetic acid |

### 2.1.2.2 Candidate(s) for substitution

Not applicable. The active substance is included in Annex 1 of BPR for product type 19 benefiting from the food and feed derogation. Biocidal products containing this type of active substances can apply under the simplified application procedure.

### 2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[2]

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
|---|---|---|---|---|---|
| Vinegar | Vinegar | Active substance | 8028-52-2 | Not applicable | 99.645<br><br>(4-5% acetic acid in biocidal product) |
| Confidential business information | Confidential business information | Non-active substance[3] | Confidential business information | Confidential business information | |

2 Please delete as appropriate.

3 Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

### 2.1.2.4 Information on technical equivalence

Not applicable. The active substance is included in Annex 1 of BPR for product type 19 benefiting from the food and feed derogation. Biocidal products containing this type of active substances can apply under the simplified application procedure.

### 2.1.2.5 Information on the substance(s) of concern

There are no substances of concern (SoC) in the biocidal product HG tegen fruitvliegjes.

From the ED properties assessment according to the UK guidance of March 2019 (CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants), summarized in the ED alerts table and the point 8 - screening tables for human health and non-target organisms (see confidential Annex), it can be concluded that none of the formulants is expected to have endocrine disrupting properties. As such it is concluded that the biocidal product does not have endocrine disrupting properties.

Please see the confidential annex 3.6 for further details confirming there are
-no SoCs
-no nano materials
-no ED properties
among the co-formulants.

### 2.1.2.6 Type of formulation

| |
|---|
| AL |

### 2.1.3 Hazard and precautionary statements[4]

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

*[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]*

| **Classification** | |
|---|---|
| Hazard category | No hazard phrases assigned |
| Hazard statement | No hazard phrases assigned |
| | |
| **Labelling** | |
| Signal words | Not applicable |
| Hazard statements | Not applicable |
| Precautionary statements | P101 If medical advice is needed, have product container or label at hand<br>P102 Keep out of reach of children |
| | |
| Note | Not applicable |

4 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

## 2.1.4 Authorised use(s)

### 2.1.4.1 Use description

Table 1. Use # 1 – Attractant

| | |
|---|---|
| **Product Type** | PT 19- Repellents and Attractans |
| **Where relevant, an exact description of the authorised use** | Attractant for indoor use |
| **Target organism (including development stage)** | *Drosophila melanogaster* (adults) |
| **Field of use** | Indoor |
| **Application method** | Open the small bottle and pour 5 mL liquid (up to the volume indication mark in the 'trap'). The trap must be placed in the room. |
| **Application rate and frequency** | Use 5 mL liquid in the trap<br>Rate of application: 5 mL/trap for 60 $m^3$ (24 $m^2$).<br>In case needed after 14 days the HG tegen fruitlviegjes must be renewed in the trap. |
| **Category of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Please see the relevant section<br>30 mL in HDPE bottle |

### 2.1.4.2 Use-specific instructions for use[5]

| |
|---|
| Open the small bottle and pour 5 ml liquid (up to the volume indication mark in the 'trap'). The trap must be placed in the room.<br><br>Rate of application: 5 mL/trap for 60 $m^3$ (24 $m^2$).<br>In case needed after 14 days the HG tegen fruitlviegjes must be renewed in the trap. |

[5] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

### 2.1.4.3 Use-specific instructions for use[6]

| |
|---|
| See general directions for use |

### 2.1.4.4 Use-specific risk mitigation measures

| |
|---|
| See general directions for use |

### 2.1.4.5 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

| |
|---|
| See general directions for use |

### 2.1.4.6 Where specific to the use, the instructions for safe disposal of the product and its packaging

| |
|---|
| See general directions for use |

### 2.1.4.7 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

| |
|---|
| See general directions for use |

[6] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

## 2.1.5 General directions for use

### 2.1.5.1 Instructions for use[7]

| |
|---|
| Open the small bottle and pour 5 mL HG tegen fruitvliegjes in the trap (up to the volume indication mark in the 'trap'). Place the trap in center where the most of the fruit flies will be present. The place where normally the fruit is being placed, for example the kitchen table. Use one trap per 60 $m^3$ (24 $m^2$). In case needed after a minimum of 14 days the HG tegen fruitlviegjes must be renewed in the trap. |

### 2.1.5.2 Risk mitigation measures

| |
|---|
| No RMM required |

### 2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

| |
|---|
| Not applicable for this biocidal product under the simplified application procedure, based on food grade vinegar. |

### 2.1.5.4 Instructions for safe disposal of the product and its packaging

| |
|---|
| Dispose off the content of the trap by emptying the solution in the sink. |

### 2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

| |
|---|
| Shelf life : 2 years |

[7] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

### 2.1.6 Other information

| |
|---|
| / |

### 2.1.7 Packaging of the biocidal product

| Type of packaging | Size/volume of the packaging | Material of the packaging | Type and material of closure(s) | Intended user (e.g. professional, non-professional) | Compatibility of the product with the proposed packaging materials (Yes/No) |
|---|---|---|---|---|---|
| Bottle | 30 ml (filled up to 20 ml) | HDPE | Screw cap made of PP | Non-professional | Yes, see stability test |
| | | | | | |

It is noted that there are two final packages both containing the above bottle(s):

1. Starter pack, including application 'pear' and one bottle
2. Re-fill pack, including two bottles

### 2.1.8 Documentation

#### 2.1.8.1 Data submitted in relation to product application

See Annex 3.1 with the reference of the product data.

#### 2.1.8.2 Access to documentation

Not relevant as this is a simplified product procedure.

## 2.2 Assessment of the biocidal product (family)

### 2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended use # 1 – name of the use[8]

| | |
|---|---|
| Product Type(s) | PT 19 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | *Drosophila melanogaster* |
| Field of use | Indoor |
| Application method(s) | Open the small bottle and pour 5 ml liquid (up to the volume indication mark in the 'trap'). The trap must be placed in the room. |
| Application rate(s) and frequency | Use 5 mL liquid in the trap<br>Rate of application: one trap per 60 $m^3$ (24 $m^2$).<br>Frequency: seasonal<br>in case needed after a minimum of 14 days the HG tegen fruitlviegjes must be renewed in the trap |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | Please see the relevant section<br>30 mL in HDPE bottle |

8 Copy this section as many times as necessary (one table per use).

## 2.2.2 Physical, chemical and technical properties

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Physical state at 20 °C and 101.3 kPa | Observation | 99.645 % Vinegar (4% and 5% acetic acid) | Clear liquid | Stienstra P.S., Derriks B, 2021a |
| Colour at 20 °C and 101.3 kPa | Observation | | Orange | |
| Odour at 20 °C and 101.3 kPa | Observation | | Vinegar / acidic | |
| Acidity / alkalinity | OECD method 122 | | pH: 2.92 (4% acetic acid<br>pH: 2.63 (5% acetic acid)<br>SDS: pH: 2.4-3.4 specification | |
| Relative density / bulk density | OECD method 109 | | Density 1.1 g/ml | |
| Storage stability test – **accelerated storage** | CIPAC method MT 46.3 2weeks at 54 °C<br><br>Method of analysis titration method | | Fresh made samples of HG tegen fruitvliegjes (4% and 5% acetic acid) were tested in commercial package.<br>No changes were observed in appearance and density.<br><br>The weight of both bottles was slightly decreased from 39.09 to 39.07 g (-0.051%). Also the pH was slightly decreased from 2.92 to 2.90 (4%) and from 2.63 to 2.60 (5%).<br><br>The acetic acid content increased with 0.03 w/w% (+0.75%) from 4.02 w/w% to 4.05 w/w% during two weeks 54°C which is acceptable<br><br>The acetic acid content increased with 0.02 w/w% | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | (+0.40%) from 4.99 w/w% to 5.01 w/w% during two weeks 54°C which is acceptable.<br><br>The generated accelerated storage stability data show that HG tegen fruitvliegjes is likely to be stable for 2 years at ambient temperature. The data also indicate that the HG tegen fruitvliegjes is stable if for intermittent periods it was subject to higher than normal temperatures. | |
| Storage stability test – **long term storage at ambient temperature** | The tests are set up according the Manual on development and use of FAO and WHO specifications for pesticides November 2010, GIFAP Technical Monograph n°17 2010 | 99.645 % Vinegar (4% and 5% acetic acid) | Protocol for two years test at ambient temperature is available. The test provided only cover the first six months. However, based on the accelerated storage test results, and the protocol provided, a stability of 2 years is approved. The final results of the long-term storage test will be provided as soon as possible at post-authorisation. | Stienstra P.S., Derriks B, 2021b |
| Storage stability test – **low temperature stability test for liquids** | CIPAC method MT 39.3; 7days at 0 °C | 99.645 % Vinegar (4% and 5% acetic acid) | Fresh made samples of HG tegen fruitvliegjes (4% and 5% acetic acid) were tested in commercial package.<br><br>For the 4% product, the acetic acid content stayed the same at 4.02 w/w%. For the 5% product, | Stienstra P.S., Derriks B, 2021c |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | the acetic acid content decreased with 0.01 w/w% (-0.20%) from 5.00 w/w% to 4.99 w/w% during 7 days 0°C, which is acceptable.<br><br>No changes were observed in appearance and density; the pH slightly decreased.<br><br>The products are stable at low termperature storage. | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | | | The effect of light is not applicable for HG tegen fruitvliegjes because the formulation is not exposed to light as packing materials are not translucent. | |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | | | The effect of humidity in not applicable for the HG tegen fruitvliegjes Because the formulation is water based. | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Part of the ambient storage stablity | 99.645 % Vinegar (4-5% in biocidal product) | No effects on weight of container plus contents were seen in the accelerated storage stability and low temperature stability studies. More details will be presented in the ongoing long term stability test. | Stienstra P.S., Derriks B, 2021a, b and c |
| Wettability | | | Not required for this formulation type and for the simplified application procedure. | |
| Suspensibility, spontaneity and dispersion stability | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Wet sieve analysis and dry sieve test | | | | |
| Emulsifiability, re-emulsifiability and emulsion stability | | | | |
| Disintegration time | | | | |
| Particle size distribution, content of dust/fines, attrition, friability | | | | |
| Persistent foaming | | | | |
| Flowability/Pourability/Dustability | | | | |
| Burning rate — smoke generators | | | | |
| Burning completeness — smoke generators | | | | |
| Composition of smoke — smoke generators | | | | |
| Spraying pattern — aerosols | | | | |
| Physical compatibility | | | Not relevant, product is RTU and not intended to be used with other products. | |
| Chemical compatibility | | | | |
| Degree of dissolution and dilution stability | | | Not required for this formulation type and for the simplified authorisation procedure. | |
| Surface tension | Not applicable | | | |
| Viscosity | Not applicable | | | |

| **Conclusion on the physical, chemical and technical properties of the product** |
|---|
| The biocidal product HG tegen fruitvliegjes is a clear orange liquid with acidic / vinegar odour. Its density is 1.1 g/mL at 20°C and 101.3 kPa . The pH of the neat product is determined at 2.4-3.4.<br>The estimated shelflife is 2 years shelflife based on results of accelerated storage stability test in commercial package. |

### 2.2.3 Physical hazards and respective characteristics

This requirement is not applicable for a simplified application (SA) procedure. The product HG tegen fruitvliegjes which is applied for under the simplified application procedure does not have physical hazards as it is based on food grade vinegar.

### 2.2.4 Methods for detection and identification

HG tegen fruitvliegjes contains vinegar as active substance. Acetic acid is considered the representative component for the active substance vinegar which can be analysed and monitored in storage stability studies.

The titration method (HG Method 34) used to determine the acetic acid concentration in the product in the storage stability studies was validated in a separate study.
For determination of linearity of the titration method six standard concentrations of acetic acid were assessed ranging from 0 to 12.0 %w/w. Also seven quantities of product sample ranging from 1.1 – 7.8 gram and seven aliquots of approximately 8.5 g vinegar bulk material were assessed.
No amount of acetic acid was found in the blank sample; no equilibrium point(s) around the expected equilibrium point for acetic acid was/were obtained.
For determination of precision, seven aliquots of the same sample (lab batch) were measured.
For determination of recovery standard addition method was applied: two aliquots of product were spiked with 0.5 and 1 %(w/w) acetic acid and mearured in duplo.
For determination of reproducibility seven aliquots of the same lab batch as for determination of precision were taken one week later and measured by a different analyst.
The validation study (see summary in IUCLID section 5) showed linearity, specificity, precision, recovery and reproducibility of the analytical method to be acceptable (see table below).

| Analytical methods for the analysis of the product as such including the active substance, impurities and residues | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Precision** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| Acetic acid | Titration with sodium hydroxide | Seven aliquots of the same sample: mean 4.47% (w/w), RSD 0.12%<br>RSD <Horwitz RSDr (1.35%) HorRat 0.089 | $r^2$=0.999<br>range 0.0 - 12.0 % w/w | No amount of acetic acid was found in the blank sample; no equilibrium point(s) around the expected equilibrium point for acetic acid was/were obtained. | Fortification level acetic acid product + 0.5% (w/w) (n=2):<br>Recovery 100.00% and 100.73%<br><br>Fortification level acetic acid product + 1% (w/w) (n=2):<br>Recovery 100.20% and 100.55% | 100.1 %<br><br>100.6 % | n.d. | LOQ: 0.15 % (w/w) | Derriks B, Stienstra P.S., 2021d<br><br>HG tegen fruitvliegjes_Method validation_calculations |

| Conclusion on the methods for detection and identificationof the product |
|---|
| The available analytical method for the determination of acetic acid, representing the active substance vinegar, in the biocidal product HG tegen fruitvliegjes is acceptable. |

## 2.2.5 Efficacy against target organisms

### 2.2.5.1 Function and field of use

PT 19 – Attractans against *Drosophila melanogaster* (adults)

HG tegen fruitvliegjes is a biocidal product containing a low risk substance as an attractant for the non-profesional use against *Drosophila melanogaster* (adults). The product is based on a food grade Vinegar (4-5% acetic acid in biocidal product).
The product is exclusively intended for: Indoor use; mass trapping of *Drosophila melanogaster* (adults)

### 2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

The product is used for the control of *Drosophila melanogaster*.

### 2.2.5.3 Effects on target organisms, including unacceptable suffering

HG tegen fruitvliegjes contains the active ingredient food grade Vinegar (4-5% acetic acid in biocidal product) which attracts the *Drosophila melanogaster* (adults) to the trap.

### 2.2.5.4 Mode of action, including time delay

HG tegen fruitvliegjes contains the active ingredient food grade Vinegar (4-5% acetic acid in biocidal product) which attracts *Drosophila melanogaster* (adults) to the trap.

## 2.2.5.5 Efficacy data

An overview of the two efficacy test which are performed is given below.
Efficacy tests have been performed with vinegar with an acetic acid concentration of 4% and vinegar with an acetic acid concentration of 5%, which results in an efficacy concentration range between 4% and 5% acetic acid. Both test have been performed with an identical trap.

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>Attractant</td><td>Indoor use</td><td>HG tegen fruitvliegjes – 4% acetic acid</td><td>Drosophila melanogaster<br><br>5 replicates of 200 insects (4 to 6 days old mixed sex adults (ratio 50/50)</td><td>Simulated-use trial<br><br>Guidance on the Biocidal Products Regulation - Volume II Efficacy – Assessment and Evaluation (Parts B&C) – Version 3.0 – April 2018 - ECHA”</td><td>5mL of product per trap (pear shaped trap)<br><br>Test chamber and conditions:<br>Size: 6m*4m*2.5m (60m$^3$ – 24 m$^2$)<br>T°: 24°C+/- 2°C<br>RH: 65% +/- 5%<br>No ventilation<br><br>After 30 minutes of acclimatization of the insects, the trap is placed in the centre of the room at a distance of 20 cm from the competition food to determine the ability of the trap to attract the insects away from the competition food. The competition food is placed on a table at a 1 m height in the centre of the chamber<br><br>The number of insects trapped is recorded by</td><td>Results:<br><br>% trapped Drosophila melanogaster<br><table><tr><td>Date</td><td>After 1h</td><td>After 2h</td><td>After 4h</td><td>After 24h</td><td>After 48h</td></tr><tr><td>Opening</td><td>24%</td><td>88%</td><td>100%</td><td>100%</td><td>100%</td></tr><tr><td>+1week</td><td>21%</td><td>80%</td><td>100%</td><td>100%</td><td>100%</td></tr><tr><td>+2weeks</td><td>15%</td><td>62%</td><td>100%</td><td>100%</td><td>100%</td></tr></table>Comments:<br><br>Time of exposure to trop 100% of insects is 4 hours.<br>The negative control series showed a low trapping rate of the insects during the trial (< 10%): the trial is validated.<br>There was no escape of the insects after trapping.<br><br>Conclusion:<br><br>HG tegen fruitvliegjes – 4% acetic acid have proved an efficacy against the fruit flies (Drosophila melanogaster) until 2 weeks after opening.</td><td>B. Serrano (December 09, 2020) – Report 2611a/1020 - “Simulated-use trial of the efficacy of a fruit fly trap”</td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td></td><td></td><td>the experimenter and the sex of the trapped flies is determined.<br>Between each test, the room is washed and an air exhauster is activated overnight.<br><br>Negative control:<br>The same trial is conducted with the same trap without the attractant (only water).</td><td></td><td></td></tr>
<tr><td>Attractant</td><td>Indoor use</td><td>HG tegen fruitvliegjes – 5% acetic acid</td><td>Drosophila melanogaster<br><br>5 replicates of 200 insects (4 to 6 days old mixed sex adults (ratio 50/50)</td><td>Simulated-use trial<br><br>Guidance on the Biocidal Products Regulation - Volume II Efficacy – Assessment and Evaluation (Parts B&C) – Version 3.0 – April 2018 - ECHA”</td><td>5mL of product per trap (pear shaped trap)<br><br>Test chamber and conditions:<br>Size: 6m*4m*2.5m (60m$^3$ – 24 m$^2$)<br>T°: 24°C+/- 2°C<br>RH: 65% +/- 5%<br>No ventilation<br><br>After 30 minutes of acclimatization of the insects, the trap is placed in the centre of the room at a distance of 20 cm from the competition food to determine the ability of the trap to attract the insects away from the competition food. The competition food is placed on a table at a 1 m height in the centre of the chamber<br><br>The number of insects trapped is recorded by</td><td>Results:<br><br>% trapped Drosophila melanogaster<br><br><table><tr><td>Date</td><td>After 1h</td><td>After 2h</td><td>After 4h</td><td>After 24h</td><td>After 48h</td></tr><tr><td>Opening</td><td>34%</td><td>91%</td><td>100%</td><td>100%</td><td>100%</td></tr><tr><td>+1week</td><td>30%</td><td>89%</td><td>100%</td><td>100%</td><td>100%</td></tr><tr><td>+2weeks</td><td>20%</td><td>69%</td><td>100%</td><td>100%</td><td>100%</td></tr></table><br>Comments:<br><br>Time of exposure to trop 100% of insects is 4 hours.<br>The negative control series showed a low trapping rate of the insects during the trial (< 10%): the trial is validated.<br>There was no escape of the insects after trapping.<br><br>Conclusion:<br><br>HG tegen fruitvliegjes – 5% acetic acid have proved an efficacy against the fruit flies (Drosophila melanogaster) until 2 weeks after opening.</td><td>B. Serrano (December 09, 2020) – Report 2611b/1020 - “Simulated-use trial of the efficacy of a fruit fly trap”</td></tr>
</table>

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | the experimenter and the sex of the trapped flies is determined.<br>Between each test, the room is washed and an air exhauster is activated overnight.<br><br>Negative control:<br>The same trial is conducted with the same trap without the attractant (only water). | | |

| **Conclusion on the efficacy of the product** |
|---|
| In accordance with the submitted tests and the requirements of the TNsG on product evaluation for PT 19, HG tegen fruitvliegjes (4% and 5% acetic acid) has shown sufficient efficacy against the fruit flies (*Drosophila melanogaster)* until 2 weeks after filling the trap. |

### 2.2.5.6 Occurrence of resistance and resistance management

Resistance is not evolving because the insect are trapped and are not escaping from the trap.

### 2.2.5.7 Known limitations

No limitations on the efficacy have been observed during testing

### 2.2.5.8 Evaluation of the label claims

eCA assessed that the product HG tegen fruitvliegjes, has shown a sufficient efficacy for the use claimed:

Indoor use by non-professionals against *Drosophila melanogaster* (adults) at an application rate of 5 mL/trap with a residual efficacy of 2 weeks and a maximum area to be treated of 60 $m^3$ (24 $m^2$).

### 2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product

The product is not intended to be used in combination with other biocidal products.

### 2.2.5 Risk assessment for human health

This requirement is not applicable for a simplified application (SA).

### 2.2.6 Risk assessment for animal health

This requirement is not applicable for a simplified application (SA).

### 2.2.7 Risk assessment for the environment

This requirement is not applicable for a simplified application (SA).

### 2.2.8 Measures to protect man, animals and the environment

For this simplified application (SA) of HG tegen fruitvliegjes no measures to protect man, anmials and the environment are required.

### 2.2.9 Assessment of a combination of biocidal products

This biocidal product is not intended to be authorised for the use with other biocidal products.

### 2.2.10 Comparative assessment

This requirement is not applicable for a simplified application (SA).

# 3 ANNEXES[9]

## 3.1 List of studies for the biocidal product (family)

| Section No / Reference No | Author | Year | Title<br>Source (where different from company)<br>Company, Report No.<br>GLP (where relevant)<br>Published or Unpublished |
|---|---|---|---|
| 1 (confidential) | | | SDS formulants |
| 3.1 to 3.4 | Stienstra P.S., Derriks B | 2021a | HG tegen fruitvliegjes accelerated storage test (CIPAC MT 46.3)<br>HG International BV<br>Damsluisweg 70, 1303 AB, Almere, The Netherlands<br>13-01-2021<br>HG Report 2<br>GLP not applicable<br>Not published |
| 3.4.1.1 | Stienstra P.S., Derriks B | 2021b | HG tegen fruitvliegjes long term storage test<br>HG International BV<br>Damsluisweg 70, 1303 AB, Almere, The Netherlands<br>13-01-2021<br>HG Report 3<br>GLP not applicable<br>Not published |
| 3.4.1.1 | Stienstra P.S., Derriks B | 2021c | HG tegen fruitvliegjes low temperature storage test (CIPCA MT 39.3)<br>HG International BV<br>Damsluisweg 70, 1303 AB, Almere, The Netherlands<br>12-01-2021<br>HG Report 1<br>GLP not applicable<br>Not published |
| 5 | Derriks B, Stienstra P.S. | 2021d | HG tegen fruitvliegjes method validation for determining active component acetic acid<br>HG International BV<br>Damsluisweg 70, 1303 AB, Almere, The Netherlands<br>20-01-2021<br>HG Report 4<br>GLP not applicable<br>Not published |
| 5 | Anonymous | 2021 | HG tegen fruitvliegjes_Method |

[9] When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

| Section No / Reference No | Author | Year | Title<br>Source (where different from company)<br>Company, Report No.<br>GLP (where relevant)<br>Published or Unpublished |
|---|---|---|---|
| | | | validation_calculations<br>HG International BV<br>Damsluisweg 70, 1303 AB, Almere, The Netherlands<br>2021<br>GLP not applicable<br>Not published |
| 6.7 | Serrano, B | 2020a | Simulated-use trial of the efficacy of a fruitfly trap HG tegen fruitvliegjes – 4% acetic acid<br>Laboratoire T.E.C.<br>1, rue Jules Vedrines, ZAC Maignon, 64600 Anglet, France<br>November 2020<br>Report 2611a/1020<br>GLP not applicable<br>Not published |
| 6.7 | Serrano, B | 2020b | Simulated-use trial of the efficacy of a fruitfly trap HG tegen fruitvliegjes – 5% acetic acid<br>Laboratoire T.E.C.<br>1, rue Jules Vedrines, ZAC Maignon, 64600 Anglet, France<br>November 2020<br>Report 2611b/1020<br>GLP not applicable<br>Not published |
| 13 | Anonymous | 2021 | SDS HG tegen fruitvliegjes<br>HG International BV<br>Damsluisweg 70, 1303 AB, Almere, The Netherlands |

## 3.2 Output tables from exposure assessment tools

Not applicable.

## 3.3 New information on the active substance

Not applicable.

## 3.4 Residue behaviour

Not applicable.

## 3.5 Summaries of the efficacy studies (B.5.10.1-xx)[10]

The available efficacy data are summarized in IUCLID.

## 3.6 Confidential annex

See below.

## 3.7 Other

Not applicable.

10 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

# Confidential annex

Please see separate documents